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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/721,114	11/22/2000	Hirohiko Hirochika	MAFF-1	2997

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EXAMINER

EINSMANN, JULIET CAROLINE

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 02/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/721,114

Applicant(s)

HIROCHIKA ET AL.

Examiner

Juliet C Einsmann

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Specification

1. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.
2. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the following reason(s): Figure 4 discloses a sequence that is not properly identified with a sequence identifier. Amendment of either the detailed description of the drawings or of the drawing to properly identify the sequence is required.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-3 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 1-3 are drawn to "Polynucleotides encoding" and as such, this would include the polynucleotides as they are present in nature. Because the claims read on polynucleotides that would occur in nature, untouched by the hand of man, these claims, as broadly drawn, encompass non-statutory subject matter. This rejection may be overcome by amendment of the claims to include, for example, language clarifying that the claimed nucleic acids are intended to be isolated and/or purified nucleic acids.

4. Claims 1-3 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a substantial asserted utility or a well established utility.

Claims 1-3 are drawn to polynucleotides encoding a plant gene capable of controlling a signal transduction system for brassinosteroid hormone. The specification asserts that these polynucleotides are of use in plant breeding (p. 14). Specifically, the specification teaches that "by introducing the present polynucleotide into plants and artificially controlling various effects in which the brassinosteroid hormone is involved, it is expected that effects such as growth promotion, yield increase, quality improvement, maturation enhancement, and tolerance against biotic and abiotic stresses can be controlled... (p. 14)." However, beyond this assertion, the specification does not provide any guidance or evidence that such effects can be achieved in plants. The specification does not provide any evidence that the instant polypeptide is even able to control a signal transduction system for brassinosteroid hormone. In example 6, applicant demonstrates that wild type and mutant type rice plants respond differently to a brassinolide steroid, and assumes that it is the presence of a mutated form of instant SEQ ID NO: 2 causing such a response, but Applicant has not provided any evidence of such a causative relationship. In order to utilize the instant invention, further experimentation would be necessary to reasonably confirm the activity of the claimed polynucleotides. In genetically modified plants, the introduced transgenes are sometimes not expressed, and they can also result in co-suppression effects. None of these effects are predictable, and the mechanisms of gene silencing are still not fully understood. Thus, success in modification of gene expression or of phenotypic characteristics in plants by genetic transformation is highly unpredictable and hence significant guidance is required to practice the art without undue experimentation. Moreover, the

phenotypic characteristics that will result from expression of a given DNA construct cannot be reliably predicted. In fact, often the expected phenotypic result is not achieved. Thus, in light of the instant disclosure, the proposed utility is not considered to be substantial because further experimentation would be necessary to reasonably confirm a use for the claimed polynucleotides.

Claims 1-3 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. For all the above reasons, the disclosure is insufficient to teach one of skill in the art how to use the invention. A review of *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) clearly points out the factors to be considered in determining whether a disclosure would require undue experimentation and include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and, (8) the breadth of the claims. All of these factors are considerations when determining the whether undue experimentation would be required to use the claimed invention. As is evidence in the discussions *supra*, each of these factors has been carefully considered in the instant grounds of rejection, and it is maintained that undue experimentation would be required by the skilled artisan to use the instant invention.

Claim Rejections - 35 USC § 112

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5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The current claims are drawn to polynucleotides encoding a plant gene capable of controlling a signal transduction system for brassinosteroid hormone, the polynucleotide encoding SEQ ID NO: 2, including any polynucleotide encoding an amino acid sequence in which one or more amino acids are deleted, substituted, or added to the amino acid sequence. Claim 2 indicates that the polynucleotide is from rice, and claim 3 designates a polynucleotide "as represented by" SEQ ID NO: 1. In light of the inclusion at the end of claim 1 indicating that the claimed polynucleotide includes any polynucleotide encoding an amino acid sequence in which one or more amino acids are deleted, substituted, or added to the amino acid sequence, the claims thus encompass any and all polynucleotides encoding "capable of controlling a signal transduction system for brassinosteroid hormone" because any number of changes are allowed in the encoded amino acid sequence. Essentially, the claims provide no structural limitations because the claims allow for an unlimited number of changes to the reference sequence.

The specification teaches only a single amino acid sequence, SEQ ID NO: 2, and the cDNA (SEQ ID NO: 1) and genomic DNA (SEQ ID NO: 3) encoding SEQ ID NO: 2. Thus, applicant has express possession of only one species in a genus which comprises hundreds of

millions of different possibilities. Applicant has not described any variants of SEQ ID NO: 2, nor any polynucleotides which encode variants of SEQ ID NO: 2. For example, the prior art (Sasaki *et al.*) provides a polynucleotide encoding a hypothetical protein which comprises instant SEQ ID NO: 2 but also has an additional 328 amino acids upstream of SEQ ID NO: 2 (see Appendix 1). It is not clear if the polypeptide encoded by the nucleic acid taught by Sasaki *et al.* is the full length version of the instantly disclosed polypeptide or a variant of the instantly disclosed polypeptide. In either situation, Applicant's instant claim encompass polynucleotides such as those taught by Sasaki *et al.*, yet applicant has not demonstrated possession of such polynucleotides.

With regard to the written description, all of these claims encompass nucleic acid sequences different from those disclosed in the specific SEQ ID No:s which, for claims 1-3 include modifications by permitted by deletion, substitution, or addition for which no written description is provided in the specification. Applicant has provided no guidance as to how or where the instantly disclosed polypeptides and polynucleotides can be modified yet still retain their claimed functionality.

It is noted that in Fiers v. Sugano (25 USPQ2d, 1601), the Fed. Cir. concluded that

"...if inventor is unable to envision detailed chemical structure of DNA sequence coding for specific protein, as well as method of obtaining it, then conception is not achieved until reduction to practice has occurred, that is, until after gene has been isolated...conception of any chemical substance, requires definition of that substance other than by its functional utility."

In the instant application, only the sequences of the disclosed SEQ ID Nos are described.

Also, in Vas-Cath Inc. v. Mahurkar (19 USPQ2d 1111, CAFC 1991), it was concluded that:

"...applicant must also convey, with reasonable clarity to those skilled in art, that applicant, as of filing date sought, was in possession of invention, with invention being, for purposes of "written description" inquiry, whatever is presently claimed."

In the application at the time of filing, there is no record or description which would demonstrate conception of any nucleic acids encoding proteins modified by addition, insertion, deletion, substitution or inversion with respect to the disclosed SEQ ID No: 2 such that a different amino acid sequence is encoded which retains the ability to control a signal transduction system for brassinosteroid hormone.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-3 are indefinite over the recitation "A polynucleotide encoding a plant gene" because it is not clear how a polynucleotide encodes a plant gene. A plant gene is a polynucleotide, and a plant gene encodes a polypeptide, but a polynucleotide is not generally understood to encode a gene. Amendment of the claim to recited "A polynucleotide encoding a plant polypeptide" would overcome this rejection.

Claims 1-3 are indefinite over the recitation of "capable of controlling" because capability is a latent characteristic and the claims do not set forth the criteria by which to determine capability. That is, it is not clear whether the recited polynucleotides have the potential to control a signal transduction system or do in fact control the signal transduction

system. Amendment of the claim to read, for example, "which controls" would obviate this rejection.

Claims 1-3 are further indefinite because claim 1 appears to have conflicting limitations. On the one hand, the claim requires that the claimed polynucleotides encode an amino acid sequence from Met at position 1 to Arg at position 1057 of SEQ ID NO: 2, yet on the other hand, the claim indicates that any polynucleotide encoding an amino acid sequence in which one or more amino acids are deleted, substituted, or added is also encompassed by the claims. Thus, it is unclear if the claim reads only on polynucleotides which encode SEQ ID NO: 2, or if the claim is broader such that it reads on any polynucleotide that has the recited function of controlling a signal transduction system for brassinosteroid hormone.

Claim 3 is further indefinite over the recitation "as represented by" because it is not clear if this is open or closed claim language. Furthermore, it is not clear if the recitation of the sequence in claim 3 is subject to the inclusion statement in claim 1 which allows for additions, deletions or substitutions.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

10. Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See

MPEP § 201.15. No foreign priority documents have been received as of the writing of this office action.

11. Claims 1-3 are rejected under 35 U.S.C. 102(a) as being anticipated by Sasaki *et al.* (GenBank Accession AP001859, 27 May 2000) OR Sasaki *et al.* (EMBL Accession AP001859, 20 April 2000).

Sasaki *et al.* provide a polynucleotide which is the *Oryza sativa* genomic DNA, chromosome 1. The polynucleotide provided by Sasaki *et al.* encodes a polypeptide comprising an amino acid sequence that is 100% identical to instant SEQ ID NO: 2. With regard to Claim 3, Sasaki *et al.* specifically provide the nucleotide sequences which are the exons for the encoded polypeptide. Furthermore, it is noted that it is not clear if the deletion, substitution, and addition language of claim 1 applies to claim 3 (see 112 2nd rejections above). Thus, the nucleic acid provided by Sasaki *et al.* meets the limitations of claims 1-3.

Applicant has been provided with two different copies of the sequence disclosure provided by Sasaki *et al.* The "creation date" for an EMBL record is the date of public availability. Thus, for the EMBL record, the creation date is 20 April 2000. The GenBank record is dated 27 May 2000. In the interest of being thorough, both copies have been provided for applicant's review.

Applicant's attention is directed to the 8th coding sequence predicted by Sasaki *et al.*, beginning at nucleotide 46467. Instant SEQ ID NO: 2 is contained within the translation product of this coding sequence. Amino acids 1-1057 of instant SEQ ID NO: 2 are identical to amino acids 329-1385 of the predicted translation product. In the nucleic acid sequence taught by Sasaki *et al.*, the start codon for SEQ ID NO: 2 begins at nucleotide 52820 of the sequence

taught by Sasaki *et al.* The final ARG of SEQ ID NO: 2 is encoded at nucleotide 57465 of the sequence taught by Sasaki *et al.*


Conclusion

12. No claims are allowed.
13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C. Einsmann whose telephone number is (703) 306-5824. The examiner can normally be reached on Monday through Friday, from 9:00 AM until 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


JEFFREY FREDMAN
PRIMARY EXAMINER


Juliet C. Einsmann
Examiner
Art Unit 1655

February 14, 2002